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510(k) Summary

510(k) Number:	**K050259**
Company:	Arthrex, Inc.
Address:	1370 Creekside Blvd., Naples, FL 34108-1945
Telephone:	(239) 643-5553
Facsimile:	(239) 598-5539
Contact:	Ann Waterhouse

Trade Name:	Arthrex Bio-Pin
Common Name:	Pin
Classification:	Pin, Fixation, Smooth
Product Code:	HTY

Description:

The Arthrex Bio-Pins are manufactured using poly(L-lactide) and stainless steel in accordance with ASTM F138.

Indications for Use:

The Arthrex Bio-Pins are poly-L-Lactide based implants used to fix small bony or apical chondral fragments in the Foot, Ankle, Upper Extremities, Hand, and Wrist, where such fragments are not under tension or load-bearing. These pins are used in cases of osteochondritis dissecans and osteochondral fragments, fixation of fractures, 1st metatarsal (bunionectomy osteotomies), upper extremity fractures, cuneiform bones, inherently stable osteotomies, and fusions of the phalanges, metatarsals, metacarpals, carpal bones, tarsal bones, ankle, and wrist. The Bio-Pins can be used for inherently stable intramedullary stabilization of joint arthroplasty (resection) or fusion for the treatment of digital deformities of the foot or hand. The Bio-Pin is also used in inherently stable long bone fractures such as the femur, fibula, tibia, humerus, radius and ulna including the diaphyseal, epiphyseal, and metaphyseal areas.

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The difference between the Arthrex Bio-Pin and predicate devices with similar indications do not raise any questions regarding the safety and effectiveness of the implant. Furthermore, the materials are well characterized and have been used in predicate devices with similar indications. The devices, as designed, are as safe and effective as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Ms. Ann Waterhouse, RAC
Senior Regulatory Affairs Specialist
Arthrex Incorporated
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K050259
Trade/Device Name: Arthrex Bio-Pin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: April 19, 2005
Received: April 20, 2005

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050259

510(k) Number (if known): K050259

Device Name: Arthrex Bio-Pin

Indications for Use:

The Arthrex Bio-Pins are poly-L-Lactide based implants used to fix small bony or apical chondral fragments in the Foot, Ankle, Upper Extremities, Hand, and Wrist, where such fragments are not under tension or load-bearing. These pins are used in cases of osteochondritis dissecans and osteochondral fragments, fixation of fractures, 1st metatarsal (bunionectomy osteotomies), upper extremity fractures, cuneiform bones, inherently stable osteotomies, and fusions of the phalanges, metatarsals, metacarpals, carpal bones, tarsal bones, ankle, and wrist. The Bio-Pins can be used for inherently stable intramedullary stabilization of joint arthroplasty (resection) or fusion for the treatment of digital deformities of the foot or hand. The Bio-Pin is also used in inherently stable long bone fractures such as the femur, fibula, tibia, humerus, radius and ulna including the diaphyseal, epiphyseal, and metaphyseal areas.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use yes AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050259